

Quality Assurance Project Plan (QAPP) for

**Data and Literature Evaluation for the
EPA's Study of the Potential Impacts of Hydraulic Fracturing (HF) on Drinking Water Resources**

A. Project Management

This section addresses project management, including project background and purpose, roles and responsibilities, and key research questions and objectives.

A1. Title and Approval Sheet

QA Category: 1

Date Original QAPP submitted: August 30, 2012

Number of Pages: 14

Revision No: 0

Signatures indicate approval of this Quality Assurance Project Plan and commitment to follow the applicable procedures noted:

/s/	8/31/12
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Susan Burden, Overall Literature Review Lead	Date
/s/	8/31/12
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Jeanne Briskin, HF Study Coordinator	Date
/s/	9/4/12
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Stephen Watkins, Quality Assurance Manager, Office of Science Policy (OSP)	Date
/s/	9/4/12
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Mimi Dannel, Deputy Director, Office of Science Policy	Date

EPA does not consider this internal planning document an official Agency dissemination of information under the Agency's Information Quality Guidelines, because it is not being used to formulate or support a regulation or guidance; or to represent a final Agency decision or position. This planning document describes the quality assurance/quality control activities and technical requirements that will be used during the research study. EPA plans to publish the research study results in a draft report, which will be reviewed by the EPA Science Advisory Board. The final research report would be considered the official Agency dissemination. Mention of trade names or commercial products in this planning document does not constitute endorsement or recommendation for use.

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A3. Distribution List

This QAPP will be distributed to the US EPA employees listed in Table 1.

Table 1. QAPP distribution list.

Name	Role in Synthesis Report	Organization	Contact Information
Jeanne Briskin	HF Study Coordinator	ORD/OSP	briskin.jeanne@epa.gov (202) 564-4583
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Steve Kraemer	Water Acquisition Literature Review Lead	ORD/OSP (on detail)	kraemer.stephen@epa.gov (202) 564-0307
Nathan Wiser	Well Injection Literature Review Lead	ORD/OSP (located in Region 8)	wiser.nathan@epa.gov (303) 312-6211
Jim Weaver	Flowback and Produced Water Literature Review Lead	ORD/NRMRL/GWERD	weaver.jim@epa.gov (580) 436-8550
Chris Impellitteri	Wastewater Treatment and Waste Disposal Literature Review Lead	ORD/NRMRL/WSWRD	impellitteri.christopher@epa.gov (513) 487-2872
Megan Fleming	Water Acquisition Literature Review Assistant	ORD/OSP	fleming.megan@epa.gov (202) 564-6604
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A4. Project Organization

The organization chart for this project is depicted in Figure 1.

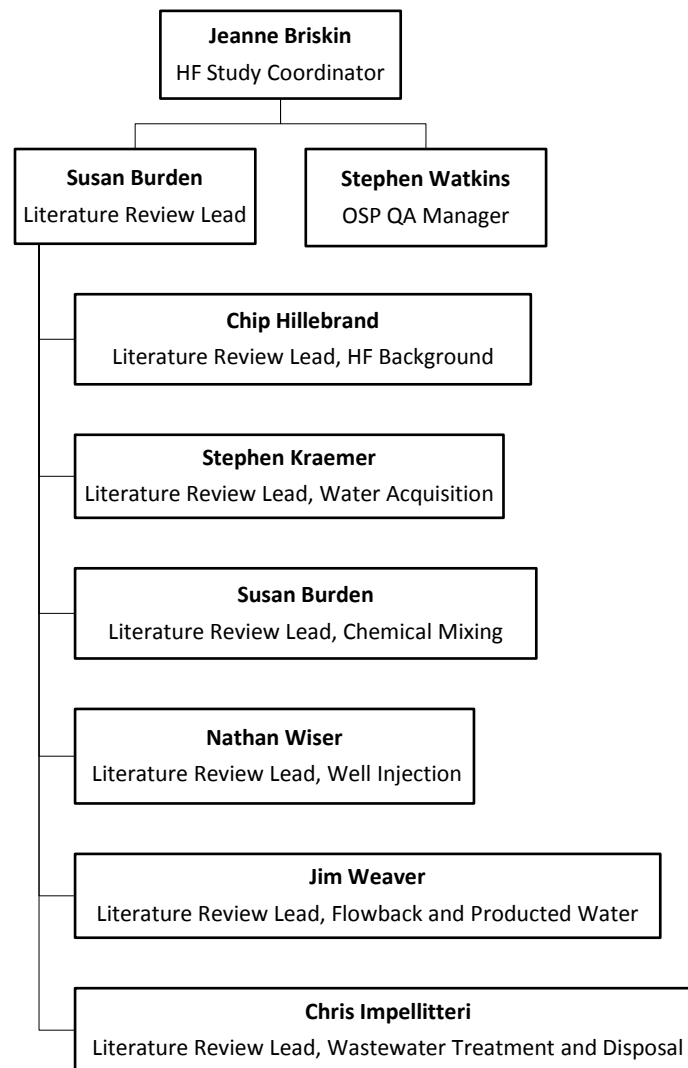


Figure 1. Organization chart for the “Data and Literature Review” project.

All Literature Review Leads are responsible for:

- review and approval of this QAPP;
- identification, review and assessment of data and literature relevant to the research questions posed in the EPA’s *Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources* (Study Plan) (US EPA, 2011);
- tracking and recording data and literature associated with this literature review; and
- conducting the verification and validation checks described in Section D2.

The Overall Literature Review Lead is responsible for keeping the OSP QA Manager and HF Study Coordinator apprised of any quality problems that arise during this project. The Overall Literature Review Lead is responsible for maintaining the QAPP throughout the course of this project.

A5. Problem Definition and Background

The objective of this project is to identify and assess data and literature relevant to the research questions outlined in the Study Plan (US EPA, 2011).

This objective will be met through two sub-objectives:

- 1) Reviewing published literature and unpublished data on the five aspects of the water cycle that define the EPA's study: water acquisition, chemical mixing, well injection, flowback and produced water, and wastewater treatment and disposal.
- 2) Incorporating completed parts of the EPA's research results on the five topics into the synthesis report.¹

This QAPP focuses on sub-objective (1) and outlines guidelines for assessing and reviewing existing data and literature. Given the potential national significance of the results of this study, the EPA researchers will need to apply a consistent, defensible approach to deciding when to include or exclude secondary data and information in the EPA's synthesis report.

A6. Project/Task Description

Literature Review Leads have been identified for each stage of the HF water cycle described in the Study Plan (US EPA, 2011). The Literature Review Leads listed in Section A4 are responsible for identifying existing data and literature relevant to the research questions associated with their stage of the water cycle.

The Literature Review Leads will identify existing literature and data using a variety of methods, including:

- use of a contractor, Eastern Research Group (ERG), to conduct an initial literature search;
- searching online databases, including OnePetro and Web of Knowledge; and
- reviewing materials provided to the EPA through technical workshops and comment submissions.

Literature Review Leads will assess the quality of secondary data and information according to five assessment factors recommended by the EPA's Science Policy Council (US EPA, 2003): soundness; applicability and utility; clarity and completeness; uncertainty and variability; and evaluation and review. These factors are described in more detail in Section A7.

¹ The EPA-funded research described in the *Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources* is being conducted under Category 1 QAPPs, which ensures that this work is done under the Agency's most rigorous QA requirements. Additional information on QA categories can be found at <http://www.epa.gov/nrmrl/qa/chapter2.html>.

Once a reference or data source is identified for inclusion in the literature review, Literature Review Leads will classify the reference/data source according to the schema identified in Section B9 and enter the citation in both EndNote® X5 and the Reference Evaluation Excel file (this process is discussed in more detail in Section A9).

A7. Quality Objectives and Criteria

Evaluating Data and Literature Sources for Inclusion: Factors for Consideration

Excerpted from US EPA (2003) A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information. US EPA Science Policy Council, Washington, DC.

“Example questions that could be raised by the consideration of each of the assessment factors for various types of information are provided below. Given the very general nature of these assessment factors, the agency felt that a compilation of such illustrative questions would most clearly convey the intended nature and breadth of the assessment factors, and how they would be reflected in an evaluation of various types of information. However, the applicability of these factors depends on the individual situation, and the EPA retains discretion to consider and use factors and approaches on a case-by-case basis that may differ from the illustrative considerations presented below.

Soundness: *The extent to which the scientific and technical procedures, measures, methods or models employed to generate the information are reasonable for, and consistent with, the intended application.*

- a) Is the purpose of the study reasonable and consistent with its design?
- b) To what extent are the procedures, measures, methods, or models employed to develop the information reasonable and consistent with sound scientific theory or accepted approaches?
- c) How do the study’s design and results compare with existing scientific or economic theory and practice? Are the assumptions, governing equations and mathematical descriptions employed scientifically and technically justified? Is the study based on sound scientific or econometric principles?
- d) In the case of a survey, have the questionnaires and other survey instruments been validated (e.g., compared with direct measurement data)? Were checks for potential errors made during the interview process?
- e) How internally consistent are the study’s conclusions with the data and results presented?

Applicability and Utility: *The extent to which the information is relevant for the agency’s intended use.*

- a) How useful or applicable is the scientific or economic theory applied in the study to the agency’s intended use of the analysis?
- b) How relevant are the study’s purpose, design, outcome measures and results to the agency’s intended use of the analysis (e.g., for a chemical hazard characterization)?
- c) Are the domains (e.g., duration, species, exposure) where the model or results are valid useful to the agency’s application?

- d) How relevant is the study to current conditions of interest? For example, in the case of a survey, are conditions likely to have changed since the survey was completed (i.e., is the information still relevant)? Is the sampled population relevant to the agency's current application? How well does the sample take into account sensitive subpopulations?

Clarity and Completeness: *The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, sponsoring organizations and analyses employed to generate the information are documented.*

- a) To what extent does the documentation clearly and completely describe the underlying scientific or economic theory and the analytic methods used?
- b) To what extent have key assumptions, parameter values, measures, domains and limitations been described and characterized?
- c) To what extent are the results clearly and completely documented as a basis for comparing them to results from other similar tests?
- d) If novel or alternative theories or approaches are used, how clearly are they explained and the differences with accepted theories or approaches highlighted?
- e) Is the complete data set accessible, including metadata, data-dictionaries and embedded definitions (e.g., codes for missing values, data quality flags and questionnaire responses)? Are there confidentiality issues that may limit accessibility to the complete data set?
- f) In the case of a modeling exercise, have the definitions and units of model parameters been provided? To what extent have the procedures for applying the model been clearly and completely documented? How available and adequate is the information necessary to run the model computer code?
- g) To what extent are the descriptions of the study or survey design clear, complete and sufficient to enable the study or survey to be reproduced?
- h) Have the sponsoring organization(s) for the study/information product and the author(s) affiliation(s) been documented?
- i) To what extent are the procedures for quality assurance and quality control of the data documented and accessible?

Uncertainty and Variability: *The extent to which the variability and uncertainty (quantitative and qualitative) in the information or in the procedures, measures, methods or models are evaluated and characterized.*

- a) To what extent have appropriate statistical techniques been employed to evaluate variability and uncertainty? To what extent have the sensitive parameters of models been identified and characterized?
- b) To what extent do the uncertainty and variability impact the conclusions that can be inferred from the data and the utility of the study? What are the potential sources and effects of error and bias in the study design?
- c) Did the study identify potential uncertainties such as those due to inherent variability in environmental and exposure-related parameters or possible measurement errors?

Evaluation and Review: *The extent of independent verification, validation and peer review of the information or of the procedures, measures, methods or models.*

- a) To what extent has there been independent verification or validation of the study method and results? What were the conclusions of these independent efforts, and are they consistent?
- b) To what extent has independent peer review been conducted of the study method and results, and how were the conclusions of this review taken into account?
- c) Has the procedure, method or model been used in similar, peer reviewed studies? Are the results consistent with other relevant studies?
- d) In the case of model-based information, to what extent has independent evaluation and testing of the model code been performed and documented?"

A8. Special Training/Certification

No special training is anticipated at the time of this writing.

A9. Documents and Records

Final documents and files generated by the Literature Review Leads are "records" and will be moved to the HF project folders on the O:\ drive when work is completed. Reference documents could be either record or non-record material, depending on how they are utilized. Items cited or referenced that support a decision/conclusion should be retained as records, and also placed in the O:\ drive, as part of the Project File. Informational copies of references or data sources are, by agency definition (EPA Schedule 008), "non-records." They will also be moved to the HF project folders when the report is completed; however, as non-records they will be retained only through project completion and then destroyed.

B. Data Generation and Acquisition

This section addresses data acquisition and management activities.

B1-B8. Sampling and Measurement Requirements

The following list of sampling and measurement requirements appears in "EPA Requirements for Quality Assurance Project Plans" (US EPA, 2002). These items were considered for this plan, but were judged non-applicable to a literature and data evaluation study.

- B1. Sampling Process Design
- B2. Sampling Methods
- B3. Sample Handling and Custody
- B4. Analytical Methods
- B5. Quality Control
- B6. Instrument/Equipment Testing, Inspection and Maintenance
- B7. Instrument/Equipment Calibration and Frequency
- B8. Inspection/Acceptance of Supplies and Consumables

B9. Non-Direct Measurements

The data needed for this project fall under the category of non-direct measurements and may include data from the following types of sources:

Peer-Reviewed Literature

- a. Journal publications
- b. Reports, white papers, fact sheets, and similar publications developed by federal and state agencies
- c. Reports on industry-sponsored research, including white papers, fact sheets, and similar publications
- d. Symposium/conference proceedings

Non Peer-Reviewed Literature

- a. Non peer-reviewed government documents
 - i. Regulations (C.F.R. or State)
 - ii. Statutes (U.S.C.)
 - iii. Court cases
 - iv. Congressional documents
 - v. Hearing proceedings
 - vi. Contractor reports
 - vii. Government reports
- b. Other types
 - i. Workshop proceedings, including the EPA-sponsored Hydraulic Fracturing Technical Workshops presented in the spring of 2010
 - ii. Master's/PhD theses
 - iii. Reports and white papers from private companies, associations, or non-governmental organizations
 - iv. Conference presentations or papers
 - v. Textbooks
 - vi. Maps
 - vii. Publications with unknown peer-review status

Unpublished Data

- a. Online databases
- b. Personal communications
- c. Unpublished manuscripts
- d. Unpublished government data

All data and existing literature will be evaluated using the guidelines given in Section A7 of this QAPP. It is expected that information included in the synthesis report will be drawn primarily from peer-reviewed publications. These publications will be viewed generally as containing the most reliable information,

particularly if most of the criteria in Section A7 are met. High reliability will be ascribed to publications with high levels of review and evaluation and where extensive tabulation of supporting information is often available. Similarly, some agencies (e.g., EPA, USGS, etc.) are known to follow extensive quality assurance and review procedures for documents they produce. Professional experience and judgment, however, will be applied to interpret results from any publication as material may be published that contains errors or adheres to outdated theory. Thus, a critical review of the literature is expected, which may point out limitations of published works, errors, and gaps in existing information.

Non peer-reviewed publications may provide useful information as long as they enhance understanding from peer-reviewed sources, or if peer-reviewed sources prove too scarce or insufficient to answer the research questions by themselves. Since workshop and conference papers may be abbreviated, and may present works-in-progress, these are not expected to form the sole basis of conclusions presented in the report. Generally, these publications may be of most use to support results presented from peer-reviewed work, to identify promising ideas of investigation and to discuss further in-depth work needed.

Portions of the report may contain compilations of data from a variety of sources. In some cases, the quality of these data may not strictly meet the guidelines outlined in Section A7, but still provide valuable information. The Literature Review Leads are responsible for deciding whether to include these data and for providing all available background information on these data in order to place these results in the appropriate context.

B10. Data Management and Hardware/Software Configuration

Reference Evaluation Excel File

All references included in the report should be tracked using the “Reference Evaluation” Excel file, which can be found in O:\Priv\NRP_SSWR_HF\008a_Non-Record_Materials\HF-Technical_Reference_Materials (008a)\Literature_for_Reference (008a). A blank version of this template can be found in Appendix 1. The template includes fields for full citation, storage location and reference type. Attribute criteria (described in Section A7) are also listed in the Excel file. For each key reference, the Literature Review Lead must rate each criterion as either “acceptable,” “marginal,” “unacceptable,” “not applicable” or “indeterminate.”

EndNote®

All literature and data sources used in the report should be entered into EndNote® X5 using a modified Standard Reference Library according to the source types listed in Section B9. This modification is described in the “Citation Types V2” Excel file found in O:\Priv\NRP_SSWR_HF\008a_Non-Record_Materials\HF-Technical_Reference_Materials (008a)\Literature_for_Reference (008a). When including PDFs of references, Literature Review Leads should use the following file naming convention:

PrimaryAuthorLastName_Topic_SourceAbbreviation_YearPublished.pdf

File names should be kept as short as possible to prevent violating file name lengths when placed on the O:\ drive. The Overall Literature Review Lead will ensure that a list of Source Abbreviations mapped to the full name of the source is maintained.

Monitoring Procedures

The Overall Literature Review Lead will review what literature is being identified for inclusion in the synthesis report in order to ensure that selection criteria are being applied to potential sources of information in a balanced and consistent manner. This will involve monitoring the information entered in the Reference Evaluation Excel file by the other Literature Review Leads, and addressing inconsistencies or disagreements during project conference calls. Any issues that cannot be resolved among the Literature Review Leads will be brought to the attention of the Study Coordinator. Additionally, the Overall Literature Review Lead will ensure that all data and literature sources are entered into EndNote® X5 and records and non-records are properly stored on the agency's designated O:\ drive for this project.

C. Assessment and Oversight

This section describes the audits and other assessments needed to determine whether this QAPP is being implemented as approved and to increase confidence in the information obtained and produced as a result of this project.

C1. Assessments and Response Actions

The OSP QA Manager will conduct a Technical Systems Audit of the writing team early on in the literature review process in order to evaluate how the literature selection process outlined in this project plan is carried out and to ensure that the Literature Review Leads are adhering to the practices outlined in the QAPP. As stated in Section B10, the Literature Review Leads are responsible for ensuring that all data and literature sources entered into EndNote® X5, and that records and non-records are properly stored on the agency's designated O:\ drive for this project. Throughout the report writing process, the QA Manager will inspect the report team's Reference Evaluation file, the records and non-records stored on the project's O:\ drive, and the literature sources entered into EndNote® X5. Problems will be discussed with the team and reported to the Study Coordinator. Any necessary corrective actions will be monitored by the QA Manager.

C2. Reports to Management

Progress will be discussed during project conference calls. Literature Review Leads will ensure that the quality criteria are applied in a consistent manner. Any inconsistencies in applying quality criteria that develop will be discussed with the Overall Literature Review Lead and reported to the Study Coordinator.

D. Data Validation and Usability

This section addresses the quality of the completed final report to see if this product will conform to the objectives outlined in this QAPP, especially given this project's use of existing datasets.

D1. Data Review, Verification, and Validation

This QAPP identifies two areas for data review, verification and validation: data transcription and report citations. Methods for conducting these reviews are described in Section D2.

Additionally, the Overall Literature Review Lead will ensure that the Reference Evaluation Excel file is checked against the references and data sources listed in the synthesis report. This process will ensure that all references and data sources included in the report have been reviewed according to the criteria listed in Section A7.

D2. Verification and Validation Methods

Data Transcription

All tables and figures created from existing literature and data sources will undergo an appropriate review process to ensure that the data were correctly transcribed, which will be organized by the relevant Literature Review Lead. This process will include checking the created tables and figures against the original sources.

Report Citations

References cited in the synthesis report will be verified by the Literature Review Leads primarily through cross-checking of each other's report sections. During the verification process, the report text associated with the selected citations will be checked against the original sources to ensure that the report text accurately reflects the information in the original source. The Project QA Manager may also assist in verifying citations in the synthesis report as needed.

D3. Reconciliation with User Requirements

References and data sources that do not strictly meet the criteria listed in Section A7 may still be included in the synthesis report at the discretion of the Literature Review Leads, particularly with respect to data that have not undergone external peer review (e.g., data collected by states or industry). The Literature Review Leads are responsible for deciding to include these data, documenting the rationale for inclusion and providing all available background information on these data in order to place these results in the appropriate context.

References

- U.S. Environmental Protection Agency. 1997. Exposure Factors Handbook: Volume I – General Factors. Washington, DC: Office of Research and Development, National Center for Environmental Assessment; Report No. EPA/600/P-95/002Fa.
- U.S. Environmental Protection Agency. 2002. Guidance for Quality Assurance Project Plans. Washington, DC: Office of Environmental Information; Report No. EPA/240/R-02/009.
- U.S. Environmental Protection Agency. 2003. A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information. Washington, DC: Office of Research and Development, Science Policy Council; Report No. EPA/100/B-03/001.
- U.S. Environmental Protection Agency. 2011. Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources. Washington, DC: Office of Research and Development; Report No. EPA/600/R-11/122.

Revision History

Revision Number	Date Approved	Revision
0		New document

Appendix 1. Reference Evaluation Template

Table A1 provides a blank example of the rejected references tracking table found in the "Reference Evaluation" Excel file located in O:\Priv\NRP_SSWR_HF\008a_Non-Record_Materials\HF-Technical_Reference_Materials (008a)\Literature_for_Reference (008a).

Table A1. Included references tracking table.

Full Citation	Storage Location	Reference Type	Evaluation Criteria				
			Soundness	Applicability and Utility	Clarity and Completeness	Uncertainty and Variability	Evaluation and Review

The Evaluation Criteria is rated using a qualitative rating scale: Acceptable, Marginal, Unacceptable, Not Applicable, Indeterminable.